REMARKS

I. Status of the Claims

Claims 1, 5, 6 and 8-10 are pending in the application. Claims 1 and 10 have been amended and claims 2-4 and 7 have been deleted. No new matter has been entered.

II. Specification

Applicant has amended paragraph 3 on page 6, and Tables 1 and 2 in the Specification to correct the spelling of "kopovidone".

III. Rejection of Claims 1-10 Under 35 U.S.C. § 103

The rejection of claims 1-10 under 35 U.S.C. 103(a) as being unpatentable over Baichwal, A.R., WO 97/39050, in view of Moroni et al., U.S. Patent 6,465,014, and Mulye et al., U.S. Patent 6,416,786, is respectfully traversed.

The present invention, as defined in the amended claims is not taught or suggested in Baichwal, Moroni and Mulye or the combination thereof.

More specifically, the present invention is directed to a composition comprising a drug, a carrier for sustained release of the drug and a gel hydration accelerator, wherein the weight ratio of the drug : the carrier for sustained release of the drug: the gel hydration accelerator is in the range of 1 : 3~30 : 0.1~15; the carrier is a mixture of sodium alginate and xanthan gum having a weight ratio of 1 : 0.1~10;

and the gel hydration accelerator is a mixture of hydroxypropyl methylcellulose and propylene glycol alginate having a weight ratio of 1 : 0.05~20.

Thus, the inventive composition defines a specific combination of sodium alginate, xanthan gum, hydroxypropyl methylcellulose (HPMC) and propylene glycol alginate (PGA) to orally administer the drug.

Baichwal teaches a composition comprising a drug, a gelling agent (comprising xanthan gum, locust bean gum, and optionally alginate or HPMC, etc.), an ionizable gel strength enhancing agent such as organic or inorganic salts, and an inert diluent. Baichwal does not teach sodium alginate and PGA as essential ingredients and HPMC is used only as an optional component.

Similarly, Moroni teaches a composition comprising a drug, sodium alginate and propylene glycol alginate, which does not comprise xanthan gum and HPMC. Mulye teaches a composition comprising a drug, a hydrocolloid such as xanthan gum, guar gum, alginic acid or pharmaceutically acceptable salt, and a cellulose ether such as HPMC, which does not comprise PGA as an essential ingredient.

Accordingly, none of the references Baichwal, Moroni and Mulye teach or suggest a composition having the defined combination of the present invention, i.e., the drug, sodium alginate, xanthan gum, HPMC and PGA.

IV. Unexpected Results from the Remarkable Effect of the Present Invention

The inventive composition of the present invention, as claimed, exhibits an unexpectedly high sustained release effect of the drug due to the specific relative amounts thereof.

Specifically, as can be seen from Figs. 6A-8D and Table 3 of the present invention, the inventive compositions show constant zero order release rates for 24 hours and rapid gel hydration without forming a non-gelated core.

In contrast, as can be seen from Figs. 8A-8D and Table 3 of the present specification, Comparative Example 1 having no PGA and Comparative Examples 2 to 4 having relative amounts of the components which are out of the ranges defined in the present invention, do not exhibit zero order release patterns and lead to more non-gelated cores than the inventive composition.

To demonstrate the effect of the unexpected results from the inventive composition having the specific relative amounts of its components, Applicant has attached a Declaration under 37 C.F.R. § 1.132. As clearly demonstrated in the Declaration, the inventive composition exhibits a zero order release pattern whereas comparative compositions which do not satisfy the claimed ranges of the composition of the present invention, do not exhibit a zero order release pattern.

The effect, according to the present invention, cannot be achieved from the Baichwal, Moroni and Mulye references which do not teach or suggest the

constitution of the inventive composition. Accordingly, even if the references cited by the Examiner were combined, they would not suggest the specific relative amounts to achieve the unexpected results. Accordingly, the Examiner's withdrawal of the rejection of claims 1, 5, 6 and 8-10 is respectfully requested.

CONCLUSION

In view of the foregoing discussions, it is respectfully submitted that the present invention as defined in the pending claims 1, 5, 6 and 8-10 is in full compliance with all the statutory requirements, and therefore, it is earnestly requested that the Examiner's rejections be withdrawn and that the pending claims be allowed in their present form.

Respectfully submitted
For applicants,

Dated: June 14, 2007

By: _____
Eugene Lieberstein
Registration No. 24,645

CUSTOMER NO. 01109
ANDERSON KILL & OLICK, P.C.
1251 Avenue of the Americas
New York, New York 10020-1182
(212) 278-1000

CERTIFICATE OF TRANSMISSION

I hereby certify that this Amendment and Request for Reconsideration is being deposited with the United States Postal Service via EFS-Web addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on June 15, 2007.

Audrey de Souza (Typed or printed name of person mailing paper or fee)

_____ (Signature of person mailing paper or fee)